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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,354	05/10/2007	Richard M. Wright	059742-5002	2805

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EXAMINER	
BASQUILL, SEAN M	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,354	WRIGHT ET AL.	
	Examiner	Art Unit	
	Sean Basquill	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *4,13,19 and 22-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-12,14-18,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *24 Mar 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the methods of modulating XOR activity, Claims 1-21 in the reply filed on 1 June 2010 is acknowledged. Claims 4, 13, 19, and 22-25 are withdrawn as directed to non-elected inventions. Claims 1-3, 5-12, 14-18, 20, and 21 are presented for examination.

Priority

2. Applicant's claim for the benefit of a prior-filed International and U.S. provisional applications PCT/US04/31478 and 60/505,922 under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Specification

3. The listing of references on pages 63-89 of the specification as originally filed is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, or have been otherwise provided by the applicants in a properly submitted information disclosure statement, they have not been considered.

Claim Rejections - 35 USC § 112 First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3, 5, 7-12, 14, 16-18, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See*, e.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984) (holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate').

Mere indistinct terms (such as "xanthine oxidoreductase (XOR) inhibitors" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a chemical compound is claimed in purely functional terms, such as by the ability to effect inhibition or agonism of a particular enzyme or receptor. *See Univ. of Rochester v. G.D. Searle*, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not

> suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *See Univ. of Calf. V. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

It is well recognized that a description by function alone does not suffice to sufficiently describe an invention because it is only an indication of what the claimed invention does, rather than what it is. MPEP § 2163(II)(A)(3)(a), *citing Regents of the University of California v. Eli Lilly, Inc.*, 119 F.3d, 1559, 1568(Fed. Cir. 1997). An adequate written description of a chemical invention requires a precise definition, such as by structure, formula, chemical name, or physical properties. *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927 (Fed. Cir. 2004).

Here, the specification does not provide a reasonably representative disclosure of useful XOR inhibitors generally, a potentially huge genus inclusive of many different compounds having widely divergent structures. Specifically, the specification discloses only a limited number of species, for example at page 20 lines 32-33 and page 21, line 20 (reciting allopurinol, oxypurinol, tungsten, amflutizole, and BOF-4272 as particular XOR inhibitors useful in the instant invention). These are not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus. While applicants have provided a definition of what they consider essential properties to be possessed by the XOR inhibitors of their invention, see pages 18 and 19 of the specification as originally

filed, this does nothing to further delineate structure, properties, or functionality to be associated with the XOR inhibitors of the invention, aside from the aforementioned requirement that the compounds inhibit XOR activity. This amounts to the quintessential "recitation of a problem to be solved, while claiming all solutions to it previously found impermissible. *Rochester*, 358 F.3d 916 at 918.

It is critical to remember that "patents are not awarded for academic theories, no mater how groundbreaking or necessary to the later patentable inventions of others. '[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.'" *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 94 USPQ2D 1161, 1173-74 (Fed. Cir. 2010), quoting Un*iversity of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 930 (Fed. Cir. 2004). Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of "invention" – that is, conceive of the complete and final invention with all its claimed limitations – and disclose the fruits of that effort to the public. *Id.* Because applicants have provided no guidance via their disclosure to permit a skilled artisan to identify structural features which would identify XOR inhibitors useful in the instant invention, applicants have not provided sufficient description to justify support for using the entire genus of XOR inhibitors to modulate inflammation as they have currently claimed.

5. Claims1-3, 5-12, 14-18, 20, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See*, e.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984) (holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate').

Mere indistinct terms (such as "glutathione precursors" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. *See Univ. of Rochester v. G.D. Searle*, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *See Univ. of Calf. V. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. *If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation*

within that genus. See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any *combination of such identifying characteristics that distinguish the claimed invention from other materials* and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful glutathione precursors generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. In fact, the specification discloses no examples of "glutathione precursors useful in the invention as claimed, therefore it is a logical impossibility for the specification to have reasonably represented the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-12, 14-18, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by F. Chabot, *et al*, *Reactive Oxygen Species in Acute Lung Injury*, 11 EUR. RESPIR. J 745, 750-53 (1998) (hereinafter "Chabot").

As a threshold matter, the examiner has reviewed the claims and the specification as originally filed and concluded that claim language such as "inflammatory reactions involving leukocytes and leukocyte precursor cells," "an agent which modulates the expression, synthesis, degradation, secretion, release, half-life, conversion or catalysis of XOR in leukocytes and leukocyte precursor cells," and "wherein said leukocytes and leukocyte precursor cells are involved in inflammatory reactions," constitute simply a recitation of properties or qualities, for example in Claims 5, 6, and 11 respectively, which the disorders to be treated or compounds particularly claimed must necessarily possess, being as they are dependent from independent claims which necessarily include these properties. As such, the examiner does not consider this language affirmative limitations of the method claims currently presented. Put more simply, the examiner considers the instant claims as directed towards the treatment of diseases, for example acute lung injury, by the administration of an XOR inhibitor such as allopurinol. The identification of a patient suffering from a disorder such as acute lung injury, and treating them with a XOR inhibitor such as allopurinol are the only affirmatively recited method steps which the examiner can identify in the instant claims, and as such represent the affirmative limitations which the examiner must demonstrate are known to skilled artisans as of the time the instant application was filed.

Chabot indicates that Allopurinol, a known xanthine oxidoreductase inhibitor, has been used to attenuate lung injury following exposure to ischemia-reperfusion, which the skilled

artisan recognizes is a type of acute lung injury. (Pg. 750 & 753). Indeed, Allopurinol has been shown to decrease tissue damage resulting from free-radicals produced by endothelial cells, in a model of ischemic lung damage in heart-lung transplantation, which the examiner considers a form of *in vitro* contacting leukocyte and leukocyte precursor cells. (Pg. 750). The examiner believes that the Chabot reference inherently describes treatment of "inflammatory reactions involving leukocytes and leukocyte precursor cells," using "an agent which modulates the expression, synthesis, degradation, secretion, release, half-life, conversion or catalysis of XOR in leukocytes and leukocyte precursor cells," and "wherein said leukocytes and leukocyte precursor cells are involved in inflammatory reactions" because the precise compounds recited as providing such modulation are known to have been used to treat the precise disorder which applicant claims includes the various cellular involvement which is claimed.

Conclusion

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean Basquill/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612